



# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference BUNT-001-PCT		<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/BE2004/000172		International filing date (day/month/year) 02.12.2004		Priority date (day/month/year) 02.12.2003
International Patent Classification (IPC) or national classification and IPC A61P25/24, A61K31/343, A61K31/4545, G01N33/48, A61K31/00, A61P25/00, A61P25/28, A61P25/22, A61P25/16				
Applicant B&B BEHEER NV				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 13 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 21 sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand  30.09.2005		Date of completion of this report  16.03.2006		
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Blott, C  Telephone No. +49 89 2399-7538  		

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ON PATENTABILITY**

**10/580962**  
**IP20 Rec'd PCT/PTO 31 MAY 2006**  
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**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-211 as originally filed

**Claims, Numbers**

1-78 filed with telefax on 30.09.2005

**Drawings, Sheets**

1-15 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
  - ☒ claims Nos. 1-78 (in part)  
because:
    - ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
    - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
    - ☒ the claims, or said claims Nos. 1-78 (in part) are so inadequately supported by the description that no meaningful opinion could be formed.
    - ☐ no international search report has been established for the said claims Nos.
    - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
      - the written form ☐ has not been furnished
      - ☐ does not comply with the standard
      - the computer readable form ☐ has not been furnished
      - ☐ does not comply with the standard
    - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
  - ☐ See separate sheet for further details

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**Box No. IV Lack of unity of invention**

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1. ☐ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
  - ☐ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
  - ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
  - ☐ the parts relating to claims Nos. .

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-78
Inventive step (IS)	Yes: Claims	
	No: Claims	1-78
Industrial applicability (IA)	Yes: Claims	1-78
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

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**Re Item I****Basis of the report**

1. The amendments filed with the International Bureau under Article 19(1) introduce subject-matter which extends beyond the content of the application as filed, contrary to Art. 19(2) PCT. The amendments concerned are the following:
  - a) Claim 1: "...wherein said second compound is selected from the group comprising: ...acetylcholinesterase inhibitor... and tachykinin antagonist...". According to the application as originally filed (cf. description p. 34-167 and claims 47-76), combinations comprising the enumerated (second) compounds are used for the treatment of specific disorders and not for any of the diseases listed under (i)-(iv).
  - b) Claims 24, 26-29: The application as originally filed does not seem to provide any basis for the term "... (eti)levodopa/decarboxylase inhibitor ...".
  - c) Claims 45-66: "... according to claim ... 43 ...". Claims 45-66 refer to Alzheimer, but not claim 43.
  - d) Claim 76: The application as originally filed does not seem to provide any basis for item (c) "...measuring the selective affinity of a test compound to adrenergic receptors and histamine receptors...".

The amended set of claims thus is not allowable under Art. 19(2) PCT.

The following general remarks can however be made.

**Re Item III****Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

2. Claims 1-78 are not supported by the description as required by Art. 6 PCT. The claims are directed to an extremely large number of possible diseases and "second" compounds. Nevertheless, the experimental protocol disclosed in the present application only refers to the combination treatment of major depression, OCD and panic disorders with pipamperone-citalopram. No alternatives are envisaged. *5-16-8*
3. The doses defined in claims 1-78 lack clarity (Art. 6 PCT).

**Re Item IV**

**Lack of unity of invention**

4. a) The application lacks unity within the meaning of Rule 13.2 PCT.
- The problem to be solved in claims 1-24, 30-75 and 77-78 of the present application is the provision of a medicament for the treatment of diseases with an underlying dysregulation of the emotional functionality selected from (i) non-cognitive metal disorders, (II) cognitive diseases, (III) pain disorders, (iv) Parkinson disease. The proposed solution is the use of pipamperone in combination with a second compound selected from the groups enumerated in claim 1.
  - The problem to be solved in claims 25-29 is the provision of a medicament for the treatment of the underlying emotion dysregulation of Parkinson disease. The proposed solution is the use of pipamperone in combination with a levodopa/decarboxylase inhibitor compound (not mentioned in claim 1).
  - The problem to be solved in claim 76 of the present application is the provision of a method for preparing a compound having a selective D4 and 5-HT2A antagonist, reverse agonist or partial agonist activity. The corresponding method is described in claim 76.

Claims 1, 25 and 76 thus include within their scope problems and solutions which are clearly different.

The separate inventions do not seem too be linked so as to form a single general inventive concept.

It is pointed out that the use of compounds having a selective D4 and 5-HT2A antagonist, reverse agonist or partial agonist activity such as pipamperone in the treatment of diseases e.g. diseases with an underlying dysregulation of the emotional functionality such as Parkinson disease is already known to the skilled person (cf. amongst others D1-21).

b) Furthermore, the application lacks unity within the meaning of Rule 13.2 PCT for the following reasons.

The problem underlying claims 1-24, 30-75 and 77-78 of the present application is the provision of a medicament for the treatment of diseases with an underlying dysregulation of the emotional functionality selected from (i) non-cognitive metal disorders, (II) cognitive diseases, (III) pain disorders, (iv) Parkinson disease (cf. claim 1).

The proposed solution is the use of pipamperone in combination with a second

compound selected from the groups enumerated in claim 1.

Pipamperone has already been used in combination with several active agents falling within the definition of claim 1 for the treatment of diseases with an underlying dysregulation of the emotional functionality such as e.g. behavioural problems, depression, anxiety, dysthymia, psychotic disorders, bipolar disorders, mania etc (cf. amongst others D1-21).

The use of pipamperone in combination with a second compound selected from the groups cited in claim 1 can therefore not be considered as a linking technical feature between the diseases enumerated in claim 1, which all are distinct and have different causes and mechanisms, their treatments representing different technical problems with their own solutions.

There is thus no special technical feature linking the treatment of the aforementioned diseases.

Furthermore, since pipamperone has already been used in combination with several active agents falling within the definition of claim 1 for the treatment of diseases with an underlying dysregulation of the emotional functionality such as e.g. behavioural problems, depression etc, the treatment of diseases with an underlying dysregulation of the emotional functionality selected from those cited in claim 1 can no longer serve as a general inventive concept linking the different groups of combinations in claim 1, which have no other special technical feature in common.

Claim 1(-24, 30-75 and 77-78) thus includes within its scope distinct problems and distinct solutions which are clearly different.

The requirements of unity thus have not been met and there is no single inventive concept underlying the plurality of inventions.

#### **Re Item V**

#### **Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

##### **5. References:**

- D1: US-A-5 762 960 (DODMAN NICHOLAS H) 9 June 1998 (1998-06-09)
- D2: VOLMAT R ET AL: "The treatment of depressions by Cledial. Evolution and clinical state and handwriting" PSYCHOLOGIE MEDICALE 1986 FRANCE, vol. 18, no. 10, 1986, pages 1615-1622, XP009028776
- D3: SQUELART P ET AL: "Pipamperone (Dipiperon), a useful sedative neuroleptic drug in troublesome

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- chronic psychotic patients." ACTA PSYCHIATRICA BELGICA. BELGIUM 1977 MAR-APR, vol. 77, no. 2, March 1977 (1977-03), pages 284-293, XP009028314 ISSN: 0300-8967
- D4: KOCH H J ET AL: "Successful therapy of tardive dyskinesia in a 71-year-old woman with a combination of tetrabenazine, olanzapine and tiapride." INTERNATIONAL JOURNAL OF CLINICAL PRACTICE. ENGLAND MAR 2003, vol. 57, no. 2, March 2003 (2003-03), pages 147-149, XP009030046 ISSN: 1368-5031
- D5: DIEBOLD K. ET AL: "Are psychoactive-drug-induced changes in plasma lipid and lipoprotein levels of significance for clinical remission in psychiatric disorders?." PHARMACOPSYCHIATRY, (1998) 31/2 (60-67)., 1998, XP009029360
- D6: WO 98/43646 A (BROEKKAMP CHRISTOPHORUS LOUIS ;PINDER ROGER MARTIN (NL); AKZO NOBE) 8 October 1998 (1998-10-08)
- D7: PERUGI G ET AL: "EFFECTIVENESS OF ADJUNCTIVE GABAPENTIN IN RESISTANT BIPOLAR DISORDER: IS IT DUE TO ANXIOUS-ALCOHOL ABUSE COMORBIDITY?" JOURNAL OF CLINICAL PSYCHOPHARMACOLOGY, WILLIAMS AND WILKINS, US, vol. 22, no. 6, 2002, pages 584-591, XP009029358 ISSN: 0271-0749
- D8: ADLER L ET AL: "PRAXIS DER STATIONAEREN AKUTBEHANDLUNG VON MANIEN RETROSPEKTIVE VERGLEICHSUNTERSUCHUNG AN JE 100 PATIENTEN ZWEIER PSYCHIATRISCHER ZENTREN PRACTICE OF IN-PATIENT ACUTE TREATMENT OF MANIAS" FORTSCHRITTE DER NEUROLOGIE PSYCHIATRIE, STUTTGART, DE, vol. 62, no. 12, 1994, pages 479-488, XP009029389 ISSN: 0720-4299
- D9: ANSOMS C ET AL: "Sleep disorders in patients with severe mental depression: double-blind placebo-controlled evaluation of the value of pipamperone (Dipiperon)." ACTA PSYCHIATRICA SCANDINAVICA. FEB 1977, vol. 55, no. 2, February 1977 (1977-02), pages 116-122, XP009041169 ISSN: 0001-690X
- D10: LEYSEN J E ET AL: "RECEPTOR INTERACTIONS OF NEW ANTIPSYCHOTICS: RELATION TO PHARMACODYNAMIC AND CLINICAL EFFECTS" INTERNATIONAL JOURNAL OF PSYCHIATRY IN CLINICAL PRACTICE, MARTIN DUNITZ, LONDON, GB, vol. 2, no. 1, 1998, pages S03-S17, XP001009585 ISSN: 1365-1501
- D11: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1996, SCHOTTE A ET AL: "Risperidone compared with new and reference antipsychotic drugs: In vitro and in vivo receptor binding" XP002290498 Database accession no. PREV199698819913
- D12: VANHOENACKER P ET AL: "EFFICIENT EXPRESSION OF THE HUMAN DOPAMINE D4.2 RECEPTOR: POSITIVE INFLUENCE OF PIPAMPERONE ON EXPRESSION LEVELS" ABSTRACTS OF THE SOCIETY FOR NEUROSCIENCE, SOCIETY FOR NEUROSCIENCE, WASHINGTON, DC, US, vol. 26, no. 1/2, 2000, page 1, XP001181469 ISSN: 0190-5295
- D13: VIJVER VAN .DE D A M C ET AL: "ANTIPSYCHOTICS AND PARKINSON'S DISEASE: ASSOCIATION WITH DISEASE AND DRUG CHOICE DURING THE FIRST 5 YEARS OF ANTIPARKINSONIAN DRUG TREATMENT" EUROPEAN JOURNAL OF CLINICAL PHARMACOLOGY, SPRINGER VERLAG, DE, vol. 58, no. 7, 2002, pages 157-161, XP009033980 ISSN: 0031-6970
- D14: ENGELBORGH S ET AL: "AMINO ACIDS AND BIOGENIC AMINES IN CEREBROSPINAL FLUID

- OF PATIENTS WITH PARKINSON'S DISEASE" NEUROCHEMICAL RESEARCH, PLENUM PRESS, NEW YORK, US, vol. 28, no. 8, August 2003 (2003-08), pages 1145-1150, XP009031514 ISSN: 0364-3190
- D15: DATABASE EMBASE [Online] ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL; 1999, ETCHEPAREBORDA M C: "Neurocognitive and pharmacological approach to specific learning disorders" XP002312308 Database accession no. EMB-2000050033
- D16: WIRZ-JUSTICE A ET AL: "HALOPERIDOL DISRUPTS, CLOZAPINE REINSTATES THE CIRCADIAN REST-ACTIVITY CYCLE IN A PATIENT WITH EARLY-ONSET ALZHEIMER DISEASE" ALZHEIMER DISEASE AND ASSOCIATED DISORDERS, RAVEN PRESS, NEW YORK, NY, US, vol. 14, no. 4, 2000, pages 212-215, XP009029353 ISSN: 0893-0341
- D17: FAHS H ET AL: "THYMOREGULATEURS DANS L'AGITATION ET LES TROUBLES DU COMPORTEMENT CHEZ LE SUJET DEMENT A PROPOS DE HUIT CAS ANTICONVULSIVANTS AND AGGRESSIVE BEHAVIORS IN ALZHEIMER'S DISEASE. EIGHT CASES REPORTS" ENCEPHALE, PARIS, FR, vol. 25, no. 2, 1999, pages 169-174, XP009039295 ISSN: 0013-7006
- D18: GRÖZINGER M ET AL: "Melperone is an inhibitor of the CYP2D6 catalyzed O-demethylation of venlafaxine." PHARMACOPSYCHIATRY. GERMANY JAN 2003, vol. 36, no. 1, January 2003 (2003-01), pages 3-6, XP009029363 ISSN: 0176-3679
- D19: WERTH ESTHER ET AL: "Decline in long-term circadian rest-activity cycle organization in a patient with dementia." JOURNAL OF GERIATRIC PSYCHIATRY AND NEUROLOGY. 2002 SPRING, vol. 15, no. 1, April 2002 (2002-04), pages 55-59, XP009042127 ISSN: 0891-9887
- D20: DE 40 39 631 A (TROPONWERKE GMBH & CO KG) 17 June 1992 (1992-06-17)
- D21: STAHL STEPHEN M ET AL: "Examination of nighttime sleep-related problems during double-blind, placebo-controlled trials of galantamine in patients with Alzheimer's disease." CURRENT MEDICAL RESEARCH AND OPINION. APR 2004, vol. 20, no. 4, April 2004 (2004-04), pages 517-524, XP009041652 ISSN: 0300-7995

6. The present application refers to the use of pipamperone in combination with a second therapeutic agent selected from the groups enumerated in claim 1, in the treatment of diseases or disorders with an underlying dysregulation of the emotional functionality selected from the groups cited in claim 1.

The present application does not meet the requirements of Art. 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Art. 33(2) PCT, in view of D1-21.

D1 discloses combination therapies for the treatment of animal **behavioural problems** wherein **pipamperone** reduces mental **anxiety** and **clomipramine** providing sedation for the animal.

In D2, a **depressive** patient with **anxiety** was administered **medifoxamine**, **chlorazepate**, **levomepromazine**, **flunitrazepam** and **pipamperone**.

In D3, chronic schizophrenic patients with **troublesome behaviour and/or dysthymia**, received a combination of incisive neuroleptics such as **flupenthixol, haloperidol, pipothiazine, thioproperazine, trifluoperidol, penfluridol, fluphenazine decanoate, fluspirilene, and pipamperone**.

In D4, a patient with **depression**, headache and orofacial dyskinesia had been treated with **haloperidol, pipamperone, zopiclone, citalopram**.

D5 refers to a clinical study wherein **psychiatric patients with depressive or schizoaffective disorders** were administered butyrophenones e.g. butyrophenones such as **pipamperone** and tricyclics and **SSRIs**, e.g. **fluvoxamine** and lithium.

D6 discloses combination comprising **mirtazapine** and antipsychotic agent such as **pipamperone**, used for treating **psychotic disorders e.g. schizophrenia, mania, hyperactivity, substance abuse**.

D7 discloses the concurrent use of **gabapentin, carbamazepin** and **pipamperone** in the treatment of **bipolar disorders**.

D8 discloses the therapy of **manic patients** with a combination of the **neuroleptics haloperidol and pipamperone**.

D9 refers to the treatment of sleep disorders in **depressive** patients with **pipamperone** in combination with **imipramine, chlorimipramine or amitriptyline**.

D10-12 disclose the selective affinity of **pipamperone** for the **5-HT<sub>2A</sub> and D<sub>4</sub> receptors**.

D13 discloses the treatment of **Parkinson disease** with agents such as **levodopa** and the concomitant use of antipsychotic agents such as **pipamperone** to counter the psychosis as a complication.

D14 describes the treatment of **Parkinson** patients with **pergolide and/or levodopa**, or

**levodopa, selegiline and anticholinergic drugs.** Parkinson patients suffering from further cognitive deterioration were further treated with **pipamperone**.

D15 discloses the use of **pipamperone** optionally in combination with **selegiline** in the treatment of **cognitive disorder**.

In D16 patients with early onset **Alzheimer Disease** received **pipamperone** in combination with **risperidone and citalopram**.

D17 discloses combinations of **pipamperone, meprobamate, moclobemide, carbamazepine** or **pipamperone, meprobamate, zuclopenthixol, alimemazine, hydroxyzine** as anticonvulsivants and against aggressive behaviors in **Alzheimer disease**.

D18 discloses combinations of **venlafaxine and pipamperone**.

D19 discloses combinations of **pipamperone and haloperidol** or **pipamperone, lorazepam and clomethiazol** in demented patients with probable **Alzheimer disease**.

D20 discloses combination preparations consisting of (A) an active ingredient with a serotonin agonistic effect, which has a bonding strength on 5-HT 1A receptors smaller than 10000 nmol/l such as **gepirone** and (B) an active ingredient with a serotonin antagonistic effect which has a bonding strength on 5-HT2 receptors smaller than 1000 nmol/l such as **pipamperone** used in neuroprotective pharmaceuticals esp. in the treatment of cerebral ischaemia.

D21 relates to sleep disorders in **Alzheimer Disease** patients treated with **galantamine**. Some patients were simultaneously treated with **dipiperon** as antipsychotic.

7. The same reasoning appears to apply, mutatis mutandis, to the subject-matter of the corresponding independent claims 25, 76.
8. Dependent claims 2-24, 26-75, 77-78 do not seem to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see documents D1-21 and the

corresponding passages cited in the search report.

9. The following observations regarding inventive step may be added (Art. 33(3) PCT).  
The experimental protocol disclosed in the present application only refers to the combination treatment of major depression, OCD and panic disorders with pipamperone-citalopram. Further diseases and agents falling within the definition of claims 1-78 have not been tested.  
There is no substantiated basis of an inventive step for any subject-matter extending beyond these embodiments (Art. 33(3) PCT).  
Moreover, most of the "second compounds" cited in the present application are well-known in the field of activity at issue. Coadministration with said compounds does therefore not render the claimed subject-matter inventive.

**Re Item VIII**

**Certain observations on the international application**

10. According to the description "... the invention relates to the use of compounds, which have D4 and 5-HT<sub>2A</sub> antagonist, inverse agonist or partial agonist activity for the treatment of the underlying emotion dysregulation of mental disorders..." (cf. p. 4, I. 1-5). The compounds may be administered in a mono-therapeutic context (cf. p. 4, I. 28-30). These statements in the description imply that the subject-matter for which protection is sought may be different to that defined by the claims, i.e. the use of pipamperone in combination with a second therapeutic agent, thereby resulting in lack of clarity (Art. 6 PCT) when used to interpret them.
11. In view of the numerous claims and the few tests carried out, it is considered that the present application does not fulfill the requirements of conciseness in the sense of Art. 6 PCT and does not meet the criteria of Rule 6.1(a) PCT regarding the numbering of claims.